IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EILEEN WAWRZYNEK and JOSEPH WAWRZYNEK, Plaintiffs	:	CIVIL ACTION
v.	:	
STATPROBE, INC., *et al*, Defendants	:	NO. 05-1342

MEMORANDUM AND ORDER

GENE E. K. PRATTER, J. OCTOBER 25, 2007

Eileen and Joseph Wawrzynek claim that Defendant Statprobe, Inc., and other successor-Defendants, Ingenix, Inc., i3 Statprobe, UnitedHealth Group, Inc. and i3 Research (collectively, "Statprobe") are liable to them for fraud, negligence, and loss of consortium arising out of Statprobe's conduct in providing clinical trial services to Gliatech, Inc. ("Gliatech"), a medical product manufacturer of a medical device marketed as ADCON-L. Plaintiffs assert that ADCON-L, applied to Mrs. Wawrzynek in connection with spinal surgery, caused an infection in her back leading to severe decomposition of her spinal column.

In its Motion for Summary Judgment, Statprobe argues that (1) Plaintiffs' claims are barred by the statute of limitations, (2) Plaintiffs' fraud claims are preempted,[1] (3) Plaintiffs' negligence claims fail because Statprobe owes no duty, and (4) Statprobe's conduct did not proximately cause Plaintiffs' injuries.

For the reasons set forth below, Statprobe's Motion for Summary Judgment is denied.

[1]Plaintiffs filed a Motion to Strike the Affirmative Defense of Federal Preemption on December 4, 2006. This Motion was considered concurrently with Statprobe's Motion for Summary Judgment.

I. BACKGROUND FACTS

Statprobe was a bio-statistical firm and contract research organization ("CRO") that, according to its advertisement, delivered the "highest quality clinical management, data management, programming, biostatistics, medical writing and medical safety services to the pharmaceutical, biotechnology and medical device industries worldwide." (Deposition of Lora Schwab, Pl.'s Mot., Ex. Z 12:1-15:1.) Gliatech was the developer and manufacturer of ADCON-L. (Def.'s Statement of Facts ("SOF") ¶ 1.)

Gliatech hired Statprobe in June 1996 to provide services in connection with the clinical study of ADCON-L mandated by the Food & Drug Administration. The purpose of the study was to evaluate ADCON-L's use in preventing the formation of scar tissue. (Def.'s SOF ¶ 2, 8.) Under the Gliatech-Statprobe Contract (the "Contract"), Statprobe was responsible for the clinical monitoring of the study, data management of the study, programming for the study, statistical analysis for the study and medical writing services resulting in a final clinical statistical report. (Contract, Pl.'s Mot., Ex. A, p. 13.) In addition, Statprobe undertook to develop and maintain the study's randomization code. (Deposition of Mark Becker, Pl.'s Mot., Ex. F 40:10-8.) Statprobe further agreed to "monitor safety data from the study and alert [Gliatech] to any potential safety concerns, report all medical events and side effects to [Gliatech] in accordance with the Standard Operating Procedure and federal regulations." (Contract, Pl.'s Mot., Ex. A, p. 4.)

A. ADCON-L and the ADCON-L Study

ADCON-L was classified as a Class III medical device under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetics Act, a designation given to a medical device that "presents an unreasonable risk of injury or illness. " 21 U.S.C. § 360. Before a Class III medical device can be marketed to the public, the manufacturer must provide the FDA with "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360c(a)(1)(C)(I). A device is considered effective "when it can be determined based on valid scientific evidence, that in a significant portion of the population, the use of the device for its intended conditions of use, when accompanied by adequate directions for use in warning against unsafe use will provide clinically significant results." 21 U.S.C. § 360e(d)(2)(A), (B).

The manufacturer of a Class III medical device must furnish its necessary "reasonable assurances" through the FDA's premarket approval ("PMA") process. 21 U.S.C. § 360e(a); Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 442 (D.N.J. 2003). The PMA process requires manufacturers to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission" Steele, 295 F. Supp. 2d at 442 (quoting Medtronic Inc. v. Lohr, 518 U.S. 470, 477 (1996)).

The ADCON-L study was a required component of the PMA process. 21 U.S.C. §360e (c)(1)(A). The ADCON-L study was designed as a double-blinded evaluation of the development of scar tissue in patients six months after lower back surgery. Of the patients enrolled in the study, roughly equal numbers received either ADCON-L or no treatment at all. (Pl.'s Mot. 3.) The randomization code developed by Statprobe identified each patient as a member of the ADCON-L group or control (i.e., no treatment) group, and Statprobe was to maintain the key to this code until the study's completion. (Deposition of Mark Becker, Pl.'s Mot. Ex. F, 35:24-40:18.) Any deviations from the study's protocol had to be approved by the FDA. (Def.'s Mot., Ex. 1, p. 58.)

Each enrolled patient received Magnetic Resonance Imaging ("MRI") tests to determine the accumulation of scar tissue at the surgical site. (Def.'s SOF ¶ 3.) A single, blinded neuroradiologist, Dr. Jeffrey Ross (who was not permitted to know the treatment/no treatment delineations), examined the MRIs and determined whether, and to what extent, scarring had occurred. Id. at ¶ 4. Based on his evaluation, Dr. Ross then assigned a score for each patient ranging from zero (no scar) to four (maximum scar). (Pl.'s Mot. 3.) The study's protocol required Dr. Ross to record each patient's results in pen on his/her "scar score sheet," a two-page form that identified the patient's control number, level of surgery, date of evaluation, and scar score results. Id.

Upon completion of his MRI reviews, Dr. Ross forwarded the scar score sheets to Statprobe to enter into its data bank for statistical analysis. Id. at 4. To demonstrate the efficacy of ADCON-L, the study would need to result in a "P value" at or below .05, meaning that there was a 5% probability or less that its results were due to chance and not ADCON-L. Id.

As part of the PMA process, Gliatech was required to submit interim data from the study

to the FDA in mid-1997 and make a presentation of the final data to an FDA Advisory Panel on December 12, 1997. (Def.'s SOF ¶11.) The interim data taken in the summer of 1997 showed preliminarily that ADCON-L was effective. Id. at ¶ 12.

The study continued until the FDA Advisory Panel meeting of December 12, 1997, as additional scare score data was collected and processed for inclusion in the study's database. (Def.'s SOF ¶ 16.) In November 1997, Gliatech requested Statprobe to provide a "good idea of what the U.S. data looks like at this point." (Pl.'s SOF ¶17.) Statprobe supplied Gliatech's requested analysis, which revealed that ADCON-L was not effective in reducing scar tissue. Contrary to the interim data submitted approximately six months earlier, the study's more developed data produced a P value of >0.5, a figure well above the 0.05 threshold. The data showed that, of the 270 patients evaluated, extensive scarring was equal between ADCON-L and the control group, (Pl.'s SOF ¶ 18.), and that the same number of patients in each group received the worst scar score of (4).

Dr. Guoquin Su, the Statprobe statistician in charge of the ADCON-L project, agreed that ADCON-L did not demonstrate efficacy in reducing scar tissue. Id. Dr. Su prepared for and attended the December 12, 1997 FDA Advisory Panel meeting, but the data was not presented. (Def.'s SOF ¶ 19.) In fact, neither Gliatech nor Statprobe raised the issue of ADCON-L's safety or efficacy at the meeting. Statprobe contends that this was because the data was preliminary and likely to change. (Def.'s SOF ¶ 18.)

Work continued on the ADCON-L data set after the December 1997 meeting. At the suggestion of the FDA Advisory Panel, Gliatech and Statprobe conducted an "Intraobserver Reliability Study" to determine whether Dr. Ross was consistent in his assignment of scar scores. (Def.'s SOF ¶ 20.) For purposes for this Motion for Summary Judgment, Statprobe stipulates that Gliatech used this study to substitute new scar score data - data that was more favorable in showing ADCON-L to be effective - for the data that originally was generated during the course of the study. (Def.'s SOF ¶ 21.)

The process of the substitution of new data proceeded as follows. On January 8, 1998 Statprobe released the randomization code to Gliatech, thus enabling Gliatech to know which of the study's patients had ADCON-L and which did not. (Pl.'s Resp. Ex. U, Ex. T-3.) Statprobe

then froze the data base. Id. at Ex. T-1. Dr. Ross, still blinded, re-read 115 MRIs in the presence of Dr. Derrick McKinley and Lillian Shaffer, of Gliatech, both of whom were unblinded. Dr. Ross re-read the MRIs and called out the results to Dr. McKinley, who recorded the results in pencil in violation of FDA regulations and the study's protocol. Nonetheless, Dr. Ross signed the scar sheets, thus indicating his approval of the re-read scores. (Deposition of Dr. Ross, Pl.'s Resp., Ex. B, 23:9-25, 31:9-21, 46:20-47:2.) A subsequent investigation by the FDA found numerous erasures within the data.

The re-read significantly improved the apparent performance results for ADCON-L. The handwritten notes of David Thurston, head of quality control at Gliatech, indicate that the study's P value decreased from .66 for the original reads to .01 after the re-read. In other words, the probability that the data resulted from chance dropped from 66% to 1%. Furthermore, the number of ADCON-L patients receiving a maximum scar score dropped from 84 to 74, while the number of control patients receiving the maximum scar score increased from 85 to 91. (Deposition of David Thurston, Pl.'s Resp., Ex. U, 66:17-67:7; Deposition of Dr. McKinley, Pl.'s Resp., Ex. K, Ex. P-8.)

Gliatech's Ms. Shaffer forwarded the new scar score sheets to Statprobe and requested that Statprobe alter the data set, which remained frozen, to include the re-read scores. Statprobe complied and entered the new data for each patient into its database. In doing so, Statprobe failed to designate that the new data had been collected in 1998 or that it was re-read. Despite the fact that the re-read data was recorded in pencil, was represented as having been read in 1997 instead of 1998, was read after the study was unblinded, and was not read in compliance with the study's guidelines, Statprobe raised no concerns. Instead, Statprobe provided a final clinical study report that did not mention the substituted data. On May 27, 1998, the FDA gave conditional approval to Gliatech to manufacture and distribute ADCON-L.

The FDA subsequently learned of the actual activities that occurred during the ADCON-L Study. (Def.'s SOF ¶ 22.) The FDA investigated Gliatech in 2000. Gliatech, a public company, filed a Form 8-K with the Securities and Exchange Commission on October 16, 2000, disclosing that the re-read MRI data was included in the final report, and that this action was an oversight

not corrected "either by Gliatech or the CRO"[2] during the process of preparing the report. (Def.'s SOF ¶ 28.) The Department of Justice eventually prosecuted Gliatech, which entered a guilty plea in March 2002 based on its failure to submit adverse event reports, failure to maintain accurate and complete files, and submission of a false or misleading report to the FDA. (Def.'s SOF ¶ 27.) The FDA requested documents, research, and the ADCON-L data from Statprobe and visited Statprobe to interview various employees, (Def.'s SOF ¶ 23.), but neither the agency nor the Justice Department took any formal action against Statprobe. (Def.'s SOF ¶ 25.)

B. Mrs. Wawrzynek's Injury

In February 1999, Eileen Wawrzynek underwent lumbar surgery at Elkins Park Hospital. Mrs. Wawrzynek's surgery occurred after the FDA had granted conditional approval to ADCON-L, but before Gliatech had submitted the final report to the FDA. (Def.'s SOF ¶ 29.) Dr. Leonard Bruno consulted with Mrs. Wawrzynek prior to her surgery and explained that he would apply ADCON-L to prevent scar tissue formation in her spinal canal. (Deposition of Dr. Bruno, Pl.'s Resp., Ex. L, 8:5-16.) Thereafter, Dr. Bruno performed the surgery and applied ADCON-L as per his consultation with Mrs. Wawrzynek. (Def.'s SOF ¶¶ 30, 31.)

In this litigation, the parties present dueling expert opinions on the causes and chronology of Mrs. Wawrzynek's injuries after her surgery by Dr. Bruno. Defense expert Dr. Alexander Vaccaro opines that Mrs. Wawrzynek developed an infection which required a second surgery. (Def.'s SOF ¶ 32). Plaintiffs' experts assert that Mrs. Wawrzynek developed a dura leak as a result of the application of ADCON-L during her first surgery that required a second surgery. (Pl.'s SOF ¶ 32.) Despite this dispute, it is undisputed that Mrs. Wawrzynek suffered severe decomposition of her spinal column following her second surgery and that, in February 2000, she underwent two additional surgeries on her back.

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[2]The acronym CRO stands for "Contract Research Organization." Statprobe was a CRO. Gliatech worked with other CROs after the submission of the final report to the FDA (primarily on reanalysis). Gliatech also disclosed its work with these other CROs in the Form 8-K. None of the CROs were mentioned by name in the 8-K.

C. Procedural History

Mr. and Mrs. Wawrzynek filed suit against Dr. Bruno, Dr. Poporad[3], and Elkins Park Hospital on December 15, 2000, alleging medical malpractice and negligence for improper antibiotic treatment. Plaintiffs claimed that Mrs. Wawrzynek's injuries were caused by Dr. Bruno's failure to obtain an infectious disease consult before her second surgery, improper prescription of antibiotics, and failure to identify the cause of her ailment. Plaintiffs lost that suit.

On July 2, 2002, Plaintiffs initiated suit against Gliatech. The parties settled that action for an undisclosed sum. (Def.'s SOF ¶ 37.)

On March 1, 2005, just over six years after ADCON-L was first applied to Mrs. Wawrzynek's spine, Plaintiffs commenced this action against Statprobe. On September 2, 2005, the Court dismissed Plaintiffs' breach of contract claim, and reserved judgment on Plaintiffs' claims of fraud and negligence pending a more developed factual record. After completion of discovery, Defendant moved for summary judgment on the fraud and negligence claims.

II. LEGAL STANDARD

A party seeking summary judgment always bears the initial responsibility for informing the court of the basis for the motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." Id. at 325.

After the moving party has met its initial burden, "the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e). Summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at

[3] Dr. Poporad was a specialist in infectious disease.

trial." Celotex, 477 U.S. at 322. Under Rule 56, the Court must view the evidence presented on the motion in the light most favorable to the opposing party. Anderson, 477 U.S. at 255.

III. DISCUSSION

A. Statute of Limitations

Statprobe first argues that the Wawrzyneks' suit is time-barred. Although the Wawrzyneks conceded that they initiated this action on March 1, 2005, more than two years after Mrs. Wawrzynek's injury, they contend that both the discovery rule and the doctrine of fraudulent concealment tolled the statute of limitations at least until October 2003. For the reasons discussed below, the Court concludes that genuine issues of material fact remain as to whether Plaintiffs timely filed this suit.

The Court looks to Pennsylvania law to determine the applicable statute of limitations and any tolling principles. Vernau v. Vic's Market Inc., 896 F.2d 43, 45 (3d Cir. 1990). Actions to recover damages for personal injury must be commenced within two years from the date of a plaintiff's injury. 42 Pa. C.S. ¶¶ 5524-5525. However, Plaintiffs here argue that both the "discovery rule" and the doctrine of fraudulent concealment tolled the statute of limitations.

1. The Discovery Rule

The discovery rule is a judicially created device "which tolls the running of the applicable statute of limitations until that point when 'the plaintiff knows or reasonably should know: (1) that he has been injured, and (2) that his injury has been caused by another party's conduct.'" Cooney v. Booth, 2007 U.S. App. LEXIS 128, at *12-13 (3d Cir. Jan. 4, 2007) (citing Pearce v. Salvation Army, 449 Pa. Super. 654, 658, 674 A.2d 1123 (1996)). Stated differently, with the discovery rule, "the statute of limitations begins to run on the first date that the injured party possesses sufficient critical facts to put him on notice that a wrong has been committed and that he need investigate to determine whether he is entitled to redress." Id. (quoting Zeleznik v. United States, 770 F.2d 20, 23 (3d Cir. 1985)).

A plaintiff invoking the discovery rule bears the burden of proving her inability to know sufficient facts to assert a claim within the straight-forward limitations period against a defendant despite her exercise of reasonable diligence. Dalrymple v. Brown, 549 Pa. 217, 224 (Pa. 1997) (citing Pocono Int'l. Raceway, 503 Pa. 80, 84-85 (Pa. 1983)). Reasonable diligence is

defined as "a reasonable effort to discover the cause of an injury under the facts and circumstances presented in the case." Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995). The Pennsylvania Supreme Court has posited that asking "what might [the plaintiff] have known, by use of the means of information within his reach, with the vigilance the law requires of him?" can appropriately lead to a determination of whether the plaintiffs were reasonably diligent, and therefore whether the discovery rule was applicable. Fine v. Checcio, 870 A.2d 850, 858 (Pa. 2005).

The point at which a plaintiff should reasonably be aware of her injury and its cause generally is an issue of fact for the jury. Accordingly, the Court may enter summary judgment only if "the undisputed facts lead unerringly to the conclusion that the time it took to discover an injury was unreasonable as a matter of law." Abbdulaziz, 2001 U.S. Dist. Lexis 16972, at * 20 (quoting A. McD. v. Rosen, 423 Pa. Super. 304, 308 (Pa. 1993); Kingston Coal Co. v. Felton, 456 Pa. Super. 270, 279, 690 A.2d 284, 288 (Pa. 1997) ("Where the facts are so clear that reasonable minds cannot differ as to whether the plaintiff should reasonably be aware that he suffered an injury, the commencement of the limitations period may be determined as a matter of law.")

In the Court's September 2, 2005 Memorandum issued in this case, the Court suggested that the then undeveloped record created a question as to whether Statprobe's name was publicly connected with the ADCON-L U.S. clinical study, and thus whether reasonable diligence could have revealed Statprobe's involvement. Statprobe now argues that the factually developed record leads "unerringly" to the conclusion that these Plaintiffs did not exercise reasonable diligence because, if they had, they would have learned sufficient information to permit the filing of suit no later than April of 2002. Thus, Statprobe highlights Mrs. Wawrzynek's concession that she did not investigate Gliatech or ADCON-L, but did hire a lawyer in 2002 in response to her injury. (Eileen Wawrzynek Dep. 25:23-26:10.) Presumably, Statprobe equates the hiring of a lawyer with at least being open to the possibility of actionable conduct by someone or other. Statprobe contends that if at that time Plaintiffs (or their counsel) adequately researched their potential claims, they would easily have encountered several publicly available documents that would have informed them of Statprobe's role in the events underlying this suit.

The first document Statprobe cites is the Form 8-K Gliatech filed with the Securities and Exchange Commission on October 16, 2000. There, Gliatech detailed its responses to FDA inquires regarding the ADCON-L study, as well as its submission of re-read data in place of the original data to the FDA. (Def.'s Mot., Ex. 13) Statprobe points to Exhibit 99.1 of Form 8-K, where Gliatech acknowledges that "[t]he failure to note that the reread MRIs were used in the final clinical study report was an oversight, which was not corrected by Gliatech or the CRO during the process of preparing the report." Id. at 4-5. (emphasis added). Although Gliatech did not identify Statprobe by name in the 8-K, it expressly noted the complicity of some "CRO." Gliatech alludes to other CROs and other data elsewhere in the Form 8-K, but it does not distinguish their various identities or different responsibilities.

Statprobe next calls the Court's attention to an article published in *The Cleveland Plain Dealer* on August 31, 2000 that described Gliatech's submission of an improper final study report to the FDA and the FDA's subsequent investigation of Gliatech. (Def.'s Mot., Ex. 11.) Rodney E. Dausch, Gliatech's former Chief Financial Officer, states in the newspaper article that the reader of the MRI test data was employed by an outside consultant, which he did not specifically identify, and that Gliatech had used an unnamed, outside CRO for "statistical analysis" and for "processing the data." Id.

Statprobe argues that the Form 8-K and the *Plain Dealer* article, both of which Statprobe claims were sufficient to trigger the running of the statute of limitations, put Plaintiffs on notice that a "CRO" acted with Gliatech and possibly had some potential responsibility in the wrongdoing underlying this suit. Although neither publicly available document mentions Statprobe by name, Statprobe contends that Plaintiffs could have identified it as the unnamed CRO with the help of one final publicly available document – the transcript of the December 1997 FDA Advisory Panel meeting. Posted on the FDA's website in March 1998, the meeting minutes reflect Gliatech's presentation to the FDA as part of the PMA process for ADCON-L. Gliatech commented during this presentation that statistics for its European study were performed "by Statprobe, of Ann Arbor Michigan." The minutes, however, do not link Statprobe to the *U.S. study*, nor do they reveal or comment upon any statistical improprieties.

Finally, Statprobe argues that even if Plaintiffs could not have compiled these three

publicly available documents in 2000 to identify Statprobe as a potential player in causing Mrs. Wawrzynek's injuries, the availability of a cause of action was otherwise obvious by April 2002. On April 3, 2002, in connection with a suit filed by one Norman Virgil Woods against Gliatech for injuries caused by ADCON-L, Mr. Woods's counsel deposed Dr. Clark Tedford (then a vice president at Gliatech) at length about Statprobe's involvement in the testing of ADCON-L. (Def.'s Mot., Ex. 21, 220:9-233:7.) Statprobe argues that if Mr. Woods' counsel could gather enough information to identify Statprobe as a participant in the ADCON-L study, Plaintiffs, too, could have accomplished the same feat at that time in conjunction with their suit against Gliatech.

Plaintiffs argue in response that the record fully supports the inference that they timely filed suit against Statprobe, after their reasonable diligence revealed Statprobe's role and responsibility in data management for the U.S. clinical study for ADCON-L. Plaintiffs received discovery in their lawsuit against Gliatech in October 2003. Until then, Plaintiffs actively had pursued those they believed to have caused their injuries, namely , Gliatech and the medical professionals involved with the surgeries. Specifically, in December 2000, Plaintiffs filed an action against Mrs. Wawrzynek's physicians. Then, after learning in July 2002 that Gliatech pled guilty to submitting false information relating to the ADCON-L study, Plaintiffs instituted a suit against Gliatech in April 2002. That action, however, was stayed until August 29, 2003 due to Gliatech's bankruptcy. (Pl.'s Mot. Ex. V.) Plaintiffs finally received discovery in that suit in October and November of 2003, from which they allege to have uncovered the following facts:

1. Statprobe, not Gliatech, entered the original data showing ineffectiveness into the study data base;
2. Statprobe released the randomization code that "unblinded" the study;
3. Statprobe assumed responsibility for the U.S. clinical study for ADCON-L, including data management and compliance with federal regulations;
4. Statprobe, not Gliatech, substituted false data into the study data base; and
5. Statprobe, not Gliatech, prepared the U.S. study report which hid the data showing product ineffectiveness from the FDA and the public.

(Pl.'s Mot. 20.) Plaintiffs filed this suit on March 1, 2005, within two years after receiving the

discovery in the Gliatech action.

Statprobe has not proffered sufficient evidence for summary judgment purposes to prove at this point that Plaintiffs failed to exercise an acceptable level of diligence in accumulating facts to implicate Statprobe within the limitations period without resort to the discovery rule. Statprobe's arguments place a weighty responsibility on Plaintiffs to scour the nation's newspapers for information related to their suit, a responsibility not reflected in case law. Plaintiffs are residents of Pennsylvania, and while it is true that the *Plain Dealer* is the self-proclaimed "largest newspaper " in Ohio and is available online, Plaintiffs are not required as part of the concept of reasonable diligence to troll the local media of the nation's cities for possible defendants with potential responsibility for their injuries. Moreover, even if Plaintiffs had found the *Plain Dealer* article and Gliatech's Form 8-K by 2000, neither of these documents identifies Statprobe by name. Thus, Plaintiffs still would have needed to locate some other source with more information of greater specificity. Statprobe has not suggested what or where that other source might have been. Although Statprobe argues that the FDA Advisory Panel meeting minutes fill this gap, the only statement about Statprobe in the minutes is a single sentence noting Statprobe's responsibility for statistics in the *European* study concerning ACDON-L. (Def.'s Mot., Ex. 10 at STAT044250.)

As for Statprobe's reference to Mr. Woods' suit against Gliatech, it is clear that Mr. Woods had discovered that Statprobe acted as CRO for Gliatech by April 2002; however, a close reading for Dr. Tedford's testimony, with particular attention to the questions posed, indicates that Mr. Woods' counsel had no knowledge that Statprobe had some degree of control over, and some potential role in , the misconduct leading to Mr. Woods' injury. (Def.'s Mot., Ex. 22 at 220:9-233:7.) Counsel's questions in that case elicited testimony that Statprobe separated itself from Gliatech's wrongdoing, as evidenced by a letter Statprobe had sent to Gliatech stating its dissatisfaction with Gliatech's data handling and conduct in the course of study. Overall, Dr. Tedford's testimony in the Woods case depicted Statprobe as an organization that kept itself at arms length from Gliatech's methods and refused to participate in Gliatech's fraud. Moreover, Mr. Woods did not join Statprobe to his lawsuit against Gliatech, and Plaintiffs could not review the deposition transcripts taken in Mr. Woods' case until 2004, when Gliatech authorized the

release of the testimony, originally under a protective order. (Pl.'s Mot., Ex. J.)

Unlike the cases where the facts led unerringly to the determination that plaintiffs totally failed to investigate their injuries, the facts in this present case cannot lead to the single conclusion that reasonable diligence would have implicated Statprobe sooner. Compare Abbdulaziz, 2001 U.S. Dist. LEXIS 16972, at *21-22[4] (at least 46 newspapers covered alleged injuries attributable to Holmesburg medical testing, public hearings were held concerning the medical testing on prisoners before both the United States Senate Subcommittee on Health and Pennsylvania's Departments of Justice and Public Welfare, six other lawsuits were filed by former Holmesburg inmates alleging many of the same claims, with salient facts, against many of the same defendants as those in the case).

2. Fraudulent Concealment

Plaintiffs here also argue that even if the discovery rule did not toll the running of the statute of limitations, Statprobe's efforts to conceal its involvement should do so. Thus, they seek to invoke the doctrine of fraudulent concealment.

The doctrine of fraudulent concealment is based on a theory of estoppel, and provides that the defendant may not seek the protection of the statute of limitations, if through fraud or concealment, the defendant itself causes the plaintiff to relax her vigilance or deviate from her right of inquiry into the facts. Fine, 870 A.2d at 860. A defendant need not have acted with an intent to deceive because unintentional fraud or concealment is sufficient to estop the defendant from pleading that a suit is time-barred. Molineux v. Reed, 516 Pa. 398, 402-403 (Pa. 1987). The standard of reasonable diligence applies equally to the doctrine of fraudulent concealment as to the discovery rule, so "a statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its

[4] Defendants argue that under Abbdulaziz, a plaintiff is not permitted to delay the accrual of a cause of action until she has identified every party who may be liable on her claim. 2001 U.S. Dist. LEXIS 16972, at * 19. This principle, while certainly logical, was drawn from a case called Zeleznik v. U.S., 770 F.2d 20, 24 (3d Cir. 1985), which specifically limited this holding to a plaintiff's continuing search for *governmental* entities that may have caused her injury. The Third Circuit Court of Appeals recognized the limitation of the discovery rule in the context of the Federal Tort Claims Act, and held as it did due to its interpretation of the Congressional intent behind the FTCA. Zeleznik, 770 F.2d at 24. Therefore, this case does not govern here.

cause." Fine, 870 A.2d at 861.

The record shows that a jury could conclude here that Statprobe took steps to conceal its identity by preventing publication of its name in connection with Gliatech or ADCON-L. In a July 23, 1997 letter from Mark Becker, Vice President of Statprobe, to Raymond Silkaitis, Ph.D., Vice President of Gliatech, Dr. Becker states that the "working relationship [between Gliatech and Statprobe] is unsatisfactory because Gliatech routinely requests Statprobe to be a part to "bad" statistical methods." (Pl.'s Mot. Ex. F.) Dr. Becker "through this letter, request[ed] that Gliatech not use Statprobe's name in any way indicating support or approval...placed before any regulatory agency by Gliatech." Id.

Thus, at this juncture, the doctrine of fraudulent concealment bolsters Plaintiffs' arguments to avoid summary judgment. Accordingly, the Court will not prevent the jury from evaluating whether Plaintiffs' claims should be barred by Pennsylvania's two-year limitations period.

B. Preemption

Statprobe argues that even if Plaintiffs' fraud allegation is not barred by Pennsylvania's statute of limitations, it nonetheless amounts to a claim of fraud-on-the-FDA cast as a state law claim that is impliedly preempted by federal law. The Court is not persuaded that this in an appropriate case for the application of preemption principles.

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States...shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Thus, "any state law that conflicts with federal law is 'without effect.'" Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (citation omitted). Federal law may preempt, and therefore displace, state law in one of three ways: express, implied or conflict preemption. See, e.g., Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 447 (D.N.J. 2003).

The Medical Device Amendments ("MDA") contain an express preemption provision, namely § 360k(a), that prohibits states from imposing requirements different from, or in addition to, the specific federal requirements imposed on medical devices by FDA regulations. Id. (citing 21 U.S.C. § 360k(a)). The Supreme Court in Medtronic v. Lohr, 518 U.S. 470 (1996), examined the preemptive scope of § 360k(a). Considering plaintiffs' Florida state law claims of negligence

and strict liability against Medtronic, the Supreme Court held that states may provide traditional remedies for violations of common law duties, so long as those duties parallel federal requirements. Id. at 495.

The Supreme Court next addressed claims of fraud-on-the-FDA in Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), in which plaintiffs claimed injuries resulting from a Class III medical device (orthopedic bone screws). 531 U.S. at 343. Plaintiffs sued AcroMed Corp., a consulting company, much like Statprobe, that assisted the device manufacturer with "navigating the federal regulatory process for these devices." Id. Plaintiffs alleged that AcroMed made fraudulent representations to the FDA in the course of obtaining approval[5] to market the screw, and that these representations were a "but for" cause of their injuries. Id. In essence, plaintiffs argued that they were entitled to damages under state tort law because, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." Id.

The Supreme Court held that plaintiffs' claims conflicted with, and therefore were impliedly preempted by, federal law. As the basis for its holding, the Court noted that AcroMed's dealings with the FDA were "prompted" by the MDA, and that the "very subject matter of [their] statements were dictated by that statute's provisions." Id. at 348. In this context, the Court asserted that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Id. As such, unlike the scenario presented by Medtronic, which implicated "federalism concerns and the historic primacy of state regulation of matters of health and safety," the Court found no presumption against preemption existed. Id. (quoting Medtronic, 518 U.S. at 485).

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[5]Buckman, involved the "§ 510(k) process," a short form route to approval for "predicate devices," or their substantial equivalents. Predicate devices are those that already were on the market when the MDA was passed in 1976. 531 U.S. at 345. The PMA requirements are more extensive and more rigorous than the § 510(k) requirements. Therefore, the majority of courts, including in the Third Circuit, have found that the PMA process imposes specific federal requirements on a medical device to trigger preemption pursuant to the MDA. Davenport v. Medtronic, 302 F. Supp. 2d 419, 431 (E.D. Pa. 2004). See also, Michael v. Shiley, Inc., 46 F.3d 1316, 1324 (3d Cir. 1995).

Moreover, in Buckman the Court reasoned that the comprehensiveness and specificity of the § 510(k) approval regime weighed in favor of preemption. The Supreme Court found that this process imposed a variety of informational requirements on applicants pursuant to specific federal regulations, and that the PMA process required even more specific and rigorous requirements. Id. at 349. The Court also noted that § 510(k) is accompanied by a holistic enforcement regime aimed at detecting, deterring and punishing false statement made during this and related approval processes.[6] Id. (citations omitted.)

The Court further supported its decision with policy considerations. For one, the Court declined to require medical device applicants to comply with the FDA's detailed regulatory regime while being subject to the dramatic burdens imposed by the various tort regimes of the fifty states. Id. at 350. The Court also expressed its support for protecting potentially beneficial off-label uses of medical devices, ones that might be chilled if manufacturers are exposed to unpredictable civil liability. Id. In addition, the Court urged that allowing fraud-on-the FDA claims to proceed under state law theories would cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the regulators, would later be judged insufficient in state court. Id. at 351. This fear, the Court cautioned, would increase the informational burden involved with the approval process, which in turn would lengthen the already prolonged time necessary for the FDA to review and approve devices. Id.

Statprobe thus argues that Plaintiff's state law claim of fraud-on-the-FDA is preempted under Buckman. The core of the Wawrzyneks' fraud claim, as characterized by Statprobe, is that Statprobe made fraudulent statements and omissions to the FDA in the course of Gliatech obtaining approval by the FDA to market and distribute ADCON-L. Thus, Statprobe argues that its alleged wrongdoings all arise solely from PMA requirements necessary to bring a medical device to market, and, accordingly, Buckman controls, and this claim is federally preempted.

Plaintiffs counter that the present factual scenario fits into the exception to the total preemption rule of fraud-on-the-FDA claims carved out by the concurring Justices in Buckman. Where prior to the state litigation, the FDA determines that a manufacturer committed fraud and

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[6] 21 C.F.R. § 860.7.

had taken steps to remove the harm-causing product from the market, the state-law fraud claim would not "depend upon speculation as to the FDA's behavior in a counterfactual situation, but would be grounded in the agency's explicit actions." Id. at 354. The claim would therefore be permissible and , indeed, "would supplement and facilitate the federal enforcement scheme." Id.

Plaintiffs' argument that the FDA already has made a finding of fraud and wrongdoing during the PMA process for ADCON-L has merit here. This case essentially fits into the Buckman concurrence's exemption. Whlie it is true that it was Gliatech, not Statprobe, that pleaded guilty to misconduct, and that Statprobe never has admitted to, pleaded guilty to, or been found guilty of any misconduct with respect to any of its activities relating to the PMA process for ADCON-L, the Court sees no legal theory or compelling policy reason to allow Statprobe to use Gliatech and its wrongdoing as a shield. Because the FDA found that fraud and wrongdoing occurred during the ADCON-L approval process, the door to the Buckman concurrence was opened wide enough to allow *both* Gliatech and Statprobe to pass through.

Alternatively, Plaintiffs also couch the fraud they allege as fraud on the general public and medical community and not as fraud-on-the-FDA. For this distinction, Plaintiffs rely on a similar case involving ADCON-L, namely, Woods v. Gliatech, 218 F. Supp. 2d 802 (W. D. Va. 2002),[7] the very same case that Statprobe sought to use in its statute of limitations arguments. In Woods, as explained above, plaintiff Norman Woods sued Gliatech for fraud, negligence and breach of warranty arising out of an injury similar to that of Mrs. Wawrzynek. Mr. Woods specifically alleged that Gliatech reviewed the results of the U.S. clinical study of ADCON-L, realized the device's inefficacy, manipulated the data, did not disclose its findings or manipulation, and failed to report adverse medical events it discovered when ADCON-L was used on patients. Id. Gliatech moved for summary judgment arguing that Mr. Woods's claims were preempted, but the court denied Gliatech's motion and held that Mr. Woods' claims were not preempted under Buckman because he alleged that Gliatech committed a fraud against the

[7]The Woods court also relied on its finding that the conditional approval which Gliatech received did not create a specific federal requirement and therefore preemption would not apply. However, the Third Circuit Court of Appeals rejected use of this analysis in Horn v. Thoratec Corp., 376 F.3d 163, 170 (3d Cir. 2004) (PMA process imposes "requirements").

public generally and not against the FDA. Id. at 809-810. Plaintiff here makes a similar claim, albeit against Statprobe, not Gliatech. See, Compl. ¶61.[8] They claim to advance a conventional fraud claim.

To prove fraud under Pennsylvania law, Plaintiffs must show: (1) a representation; (2) which is material to the transaction at hand; (3) made falsely with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance. Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994). As the Third Circuit Court of Appeals has explained, "unlike a strict liability claim, which is predicated on the duty to produce a safe product, a fraud claim is based 'on a more general obligation – the duty not to deceive.'" Steele, 295 F. Supp. 2d at 456 (quoting Michael v. Shiley, Inc., 46 F.3d 1316, 1330 (3d Cir. 1995).

Statprobe highlights that Plaintiffs have shown no misrepresentations made to either Mrs. Wawrzynek's doctors or to Plaintiffs themselves. Unlike the fact pattern in many of the cases dealing with drug manufacturers who directly communicated with physicians and/or patients, Statprobe had no contact with doctors, patients, or Mrs. Wawrzynek. See, e.g., Taylor v. Danek Medical Inc., 1998 WL 962062 (E.D. Pa. Dec. 29. 1998) (manufacturer allegedly made fraudulent representations about the surgical device to plaintiff's physician); Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995) (defendants sent letters and promotional materials with misstatements directly to plaintiff's doctors).

Perhaps recognizing the potential lack of direct misrepresentation, Plaintiffs aver that fraud also may consist of withholding information, that is, an omission. In Pennsylvania, an omission is only fraudulent when the parties owe some duty to one another. In Harrisburg v. Bradford Trust Co., 621 F. Supp. 463, 473 (M.D. Pa. 1985), the district court explained that,

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[8]The Wawrzyneks' Complaint states: "Statprobe, Inc. purposely concealed, failed to disclose, and misstated the data with respect to the efficacy of ADCON-L both to the general public, prescribing physicians and the FDA." (Compl. ¶ 61.) Plaintiffs argue that these allegations of fraud do not emanate from the specific federal events of the PMA process, namely 21 C.F.R. §§ 312.52 and 860.7, but rather that the fraud "is based generally on the PMA process itself." (Pl.'s Mot. 32.)

"[i]n general, an omission is actionable only when there is an independent duty to disclose the omitted information. Such an independent duty exists, for example, where the party who is alleged to be under an obligation to disclose stands in a fiduciary relationship to the party seeking disclosure." (citing Federal Land Bank of Baltimore v. Fetner, 269 Pa. Super. 455, 410 A.2d 344 (1979), cert. denied, 446 U.S. 918 (1980).

Statprobe argues that any duty to disclose emanates directly from the PMA process, and, thus, it is preempted under Buckman. The Court finds, however, that because the FDA already has made a finding for fraud and wrongdoing during the PMA process for ADCON-L, Plaintiff's case may proceed under the Buckman concurrence. Because this issue is not preempted, the jury must now determine whether Statprobe was required to disclose to the public that it substituted data in the study and/or that its study revealed the inefficacy of ADCON-L.

Finally, if Plaintiffs can assert a common-law fraud claim, they would have to be able to show reliance. Plaintiffs claim that the medical community relied upon the representations of effectiveness in deciding to expose surgical patients to the risks of ADCON-L. (Pl.'s Mot. 38.) However, every doctor making use of an FDA-approved medical device relies on the FDA's having approved such a device, and consequently could be said to have "relied" on representations to the FDA and the FDA's decision with respect to a product's safety vis-a-vis its effectiveness. Of course, if that reliance is based on false (or omitted) information presented to the public via the FDA approval process, there is no concern that innocent medical manufacturers will face a barrage of lawsuits whenever an unknown and unforeseen complication arises from use of their products. Again, only manufacturers and clinical researchers that present fraudulent data to the FDA (and thus, indirectly, to the public) – those that cannot claim preemption under Buckman, but must face the courts under its concurrence – will face liability. Therefore, Plaintiffs' claims against Statprobe for fraud may proceed beyond a summary judgment attack.

C. Negligence

Plaintiffs allege that Statprobe's role in the U.S. clinical study for ADCON-L supports a claim of negligence. Statprobe, however, argues that it did not owe Mrs. Wawrzynek a duty of care, and thus Plaintiffs' claim fails as a matter of law. As discussed above and below, Statprobe has not persuaded the Court at this junction that, as a matter of law, it did not owe Plaintiffs a

legal duty.

For a plaintiff to recover on a claim of negligence under Pennsylvania law, it is axiomatic that a defendant must owe a duty or obligation to a plaintiff. Orner v. Mallick, 527 A.2d 521, 523 (Pa. 1987). Whether duty arises out of the conduct of a defendant depends upon the foreseeability of the risk that the conduct will cause a particular injury to a plaintiff. Dyson v. General Motors Corp., 298 F. Supp. 1064, 1069 (E.D. Pa. 1969). The existence of a legal duty is typically a question of law reserved for the trial court. Sharpe v. St. Luke's Hosp., 821 A.2d 1215, 1219 (Pa. 2003).

It is in light of these principles that Plaintiffs and Statprobe adopt opposing positions. Clearly, the performance of research, administration of clinical trials, and compilation of statistical data implicate the well being of third parties, such as consumers, to some extent. The threshold issue, therefore, is whether Statprobe's conduct was so remote and attenuated from Mrs. Wawrzynek and her injury, that the Court cannot impose a legal duty upon Statprobe.

Citing Staples v. Merck & Co., Inc., 270 F. Supp. 2d 833 (N.D. Tex. 2003)[9] and Artiglio v. Corning, 957 P.2d 1313 (Cal. 1998), Statprobe argues that a CRO assisting a medical device manufacturer does not owe a duty of care to individuals who may use the researched product, as the connection between a CRO and consumers is too remote to create a legal duty. In Staples, consumers sued Merck and its independent clinical researchers for negligence, fraud, and conspiracy, claiming that the researchers acted in concert with Merck in committing misdeeds with respect to the reporting of a drug's side effects. Id. at 839. The court in that case held that no duty existed between the researchers and the consumers because "generally independent laboratories have no duty of reasonable care towards parties with which they did not contract." Id. at 838.

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[9]In Staples, plaintiffs alleged negligent undertaking pursuant to § 324A of the Restatement (Second) of Torts - Liability to Third Person for Negligent Performance of Undertaking. Plaintiffs pursue the same theory here, as well as asserting that Statprobe had a duty pursuant to §§ 310 and 311 (Negligent Misrepresentation Involving Risk of Physical Harm) and § 876 (Persons Acting in Concert) of the Restatement. For the purposes of this motion, the question of law for the Court to resolve is solely whether Statprobe had a duty to Plaintiffs. If so, a jury must resolve whether Statprobe breached the duty, and whether the duty resulted in injury according to the variety of theories of negligence Plaintiffs pursue.

Statprobe contends that Plaintiffs have put forth no evidence showing that Statprobe assumed a unique role in the U.S. clinical study for ADCON-L. Similar to the clinical researchers in Staples that followed Merck's instructions and reported the results, Statprobe argues that its limited role in the study at issue here consisted of little more than data entry and running analyses at Gliatech's request. Statprobe asserts, however, that even if the Court finds that Statprobe undertook a more intimate role in the study, it nonetheless should not impose a legal duty on Statprobe because Plaintiffs' harm was an unforeseeable risk of Statprobe's conduct. In support of its position, Statprobe opines that even if it performed its analysis perfectly and showed ADCON-L to be *effective*, the device later could be found *unsafe* and thereby cause harm to consumers, a series of events that would be unforeseeable.

Statprobe criticizes Plaintiffs' reliance on DeMarco v. Lynch Homes, Inc., 583 A.2d 422 (Pa. 1990), which held a physician liable to his patient's boyfriend for failing to inform his patient that she was contagious for hepatitis prior to her sexually transmitting the disease to her boyfriend, and Troxcel v. A.I.duPont Institute, 675 A.2d 314 (Pa. Super. 1996), which held a physician liable to a third-party fetus who contracted a virus from his patient for failing to warn the patient to avoid contact with a pregnant family friend. Statprobe asserts that both DeMarco and Troxel are distinguishable, as the court in each case extended an already existing underlying duty -- the duty owed by a physician to a patient -- to a logical and identifiable third party, and not to the public at large. Statprobe highlights that in each of these two cases it was foreseeable that the physicians' negligence could harm specific third parties.

Plaintiffs, in turn, argue that the record strongly favors the imposition of a legal duty upon Statprobe. First, Plaintiffs question Staples' application here and highlight that the basis of the Texas Court's decision was that the plaintiffs had substituted conclusory allegations for sufficient facts to show that the clinical researchers assumed a duty to the plaintiffs. 270 F. Supp. 2d at 842. In Staples, the evidence showed that the clinical researchers did not negligently gather or report data and that they did not have enough control over the medical testing to draw any conclusions about the safety of the product. Id. at 841. For this reason, Plaintiffs state that the Staples court confined its decision to the facts (or lack thereof) of the case without holding that there may never be a claim of negligent undertaking successfully asserted against the researcher of a

pharmaceutical drug. Id. at 842.

Plaintiffs aver that, unlike the minor role assumed by the clinical researched in Staples, Statprobe was so involved with U.S. clinical study of ADCON-L that it should have recognized that its services were necessary to protect third persons. Plaintiffs allege that Statprobe agreed with Gliatech to do more than provide simply statistical services or crunch numbers; it assumed the entire responsibility for the study. Plaintiffs cite the Gliatech-Statprobe contract, which indicates that Gliatech hired Statprobe to perform the clinical monitoring, data management, programming, medical writing, and statistical analysis for the study, and to compile the final clinical statistical report to the FDA. (Contract, Pl.'s Mot., Ex. A.) Moreover, Statprobe agreed to maintain clinical data for the study, serve as the direct liaison for collecting data from the sole neuroradiologist conducting MRI reads, and assume responsibility for reporting any deviations from protocol to the FDA. Statprobe also developed the study's randomization code, (Schaffer Deposition, Pl.'s Mot., Ex. N 89:1-91:17; Becker Deposition, Pl.'s Mot., ex. F, 40:1-8), and it later determined when to reveal it to Gliatech. (Pl.'s Mot. - New Matter ¶ 13.)

In addition, aside from services related to the efficacy of ADCON-L's efficacy, Plaintiffs add that Statprobe's domain encompassed safety as well. Statprobe consented to "monitor[ing] safety data from the study and alert[ing] [Gliatech] to any potential safety concerns, report[ing] all medical events, and side effects in accordance with Standard Operating Procedure and federal regulations." (Contract, Pl.'s Mot., Ex. A.) Under these guidelines, Plaintiffs argue that Statprobe accepted responsibility for determining whether the data showed that ADCON-L was effective, so that the risks germane to Class III products in general and to ADCON-L in particular were subsumed by the benefits of the device.

Statprobe has not demonstrated, as a matter of law, that under the unique circumstances here it owed no duty to Plaintiffs. As Plaintiffs illustrate, Statprobe appears to have assumed a role in the U.S. clinical study for ADCON-L that involved much more than simple, remote "number crunching." Specifically in light of the fact that Gliatech (and Statprobe) knew that ADCON-L had a tendency to cause CSF leaks, Mrs. Wawrzynek cannot be said to be out of the foreseeable orbit of potential plaintiffs, nor can it be said that this orbit constitutes only the broad

category of the public at large.[10]

D. Proximate Cause

Statprobe also contends that its conduct did not proximately cause Mrs. Wawrzynek's injuries, and thus the Court should dismiss the fraud and negligence claims. Plaintiffs counter that the issue of proximate causation is disputed and should proceed to a jury.

The question of proximate cause, as measured by the "substantial factor" test, is almost always one of fact for the jury. Griggs v. BIC Corp., 981 F.2d 1429, 1439 (3d Cir. 1992). Proximate cause poses questions of law that require the Court to determine whether the defendant's negligence was so remote that, as a matter of law, it cannot be held liable for the harm which subsequently occurred. Redland Soccer Club, Inc. v. Dept. Of the Army, 55 F.3d 827, 851 (3d Cir. 1995). In general, proximate cause examines the nexus between a defendant's wrongful acts or omissions and the injury sustained. Gallo v. Federal Express, 937 F. Supp. 392, 295 (E.D. Pa. 1996). If Plaintiffs have introduced enough evidence to create a genuine issue of material fact as to causation, the case must proceed to a jury. Id. at 851.

The parties' experts present dueling opinions regarding the cause of Plaintiffs' injuries. Plaintiffs' experts opine that the ADCON-L applied by Dr. Bruno during Mrs. Wawrzynek's first surgery caused a spinal fluid leak that required a second surgery, which, in turn, produced the infection giving rise to her current injury. Plaintiffs also assert that Statprobe understood that ADCON-L was not clinically effective and that patients could be harmed by having the device placed in their bodies. Thus, Plaintiffs argue that Statprobe's negligence and fraudulent actions increased the risk that Mrs. Wawrzynek would be harmed receiving ADCON-L.

Statprobe argues that none of its alleged wrongful acts related in any way to ADCON-L's safety, and thus any fraud or negligence on its behalf could not have been the proximate cause of Plaintiffs' injuries. Statprobe refutes that ADCON-L caused Mrs. Wawrzynek's infection, and

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[10]If such orbit of potential plaintiffs constituted the entire public at large, then no actionable duty would exist. Actionable duty requires a connection between defendant and plaintiff. F. Pollock, *Law of Torts* 468 (13th ed. 1929) ("Negligence in the air, so to speak, will not do."). See also, W. Prosser, *Law of Torts* 333 (3d ed. 1964) ("'Duty' is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that a particular plaintiff is entitled to protection.").

that it statistical analysis was geared toward determining ADCON-L's tendency to produce infections. Statprobe contends that the causal chain proffered by Plaintiffs connecting Statprobe's alleged negligence and fraud with Mrs. Wawrzynek's harm demonstrates that in no way was Statprobe's behavior a substantial factor in that harm. Altogether, Statprobe argues that the relationship between Statprobe and Plaintiffs is far too remote to satisfy the requirement of proximate causation.

Because Plaintiffs have put forth sufficient evidence to create a genuine issue of material fact regarding causation, the Court will not grant summary judgment in favor of Statprobe on this ground. Statprobe had not proven that its conduct was so remote that the Court must conclude, as a matter of law, that it cannot be held liable for the harm that subsequently occurred. The issue of whether Mrs. Wawrzynek's several surgeries or her infections, and whether ADCON-L can be said to have caused a dura leak in Mrs. Wawrzynek's back (or merely failed to prevent the leak) are better considered as questions of intervening and superceding cause for a jury.

III. CONCLUSION

For the foregoing reasons, the Court denies the Defendant's Motion for Summary Judgment. An appropriate Order consistent with this Memorandum follows.

BY THE COURT:

S/Gene E.K. Pratter
GENE E.K. PRATTER
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EILEEN WAWRZYNEK and	:	CIVIL ACTION
JOSEPH WAWRZYNEK,	:	
Plaintiffs	:	
	:	
v.	:	
	:	
STATPROBE, INC., *et al*,	:	
Defendants	:	NO. 05-1342

ORDER

AND NOW, this 25th day of October, 2007, upon consideration of the Motion for Summary Judgment (Docket No. 35) filed by Defendants Statprobe, Ingenix, Inc., i3 Statprobe, UnitedHealth Group, Inc. and i3 Research, and the responses thereto; Platiniffs' Motion to Preclude the Affirmative Defense of "Learned Intermediary" (Docket No. 36); and Plaintiffs' Motion to Strike the Affirmative Defense of Federal Preemption (Docket No. 37), it is hereby ORDERED that:

1. Defendant Statprobe's Motion for Summary Judgment is DENIED;

2. Plaintiffs' Motion to Preclude the Affirmative Defense of "Learned Intermediary" is GRANTED as unopposed;[11] and

3. Plaintiffs' Motion to Strike the Affirmative Defense of Federal Preemption is GRANTED.

BY THE COURT:

S/Gene E.K. Pratter
GENE E.K. PRATTER
United States District Judge

[11]During the oral argument regarding the Motion for Summary Judgment, counsel for Defendant stated that this defense would not be pursued. Tr. at 2, lines 19-22 (Feb. 22, 2007).